K020666

JUN 2 4 2002 **510(k) SUMMARY**

Date Prepared	28 February 2002
510(k) No.	
Submitter	Baxter Healthcare Corporation Baxter BioScience 550 North Brand Boulevard Glendale, CA 91203
Contact	Arlene Vidor Vice President, Regulatory Affairs, North America
Device Name	DUPLOJECT EASY-PREP Fibrin Sealant Preparation and Application System
Common/Usual/ Classification Name	Syringe, Piston
Predicate Devices	DUPLOJECT Dual-Barreled Applicator Device 510(k) No. K973510 Baxter Healthcare Corporation, Baxter BioScience SEALOUETTE Fibrin Sealant Applicator 510(k) No. K992351 Baxter Healthcare Corporation, Baxter BioScience Needleless Transfer Device 510(k) No. K001831 Medimop Medical Projects Ltd.
Device Description	The DUPLOJECT EASY-PREP System is a collection of standard components used for the reconstitution and application of TISSEEL VH Fibrin Sealant. The system consists of the following components: two double-ended Fluid Transfer Spikes, a QUIK-FILL Syringe Filler and a pre-assembled DUPLOJECT Double-Barreled Syringe Applicator. With the exception of the fluid transfer spike, all components in the have been previously cleared via Premarket Notification submissions. The fluid transfer spike has been shown to be substantially equivalent to the predicate device (Medimop Needleless Transfer Device) through *in vitro* testing, in which the vial-to-vial transfer of fluid was shown to be equivalent in both the predicate and modified devices.
Intended Use	The DUPLOJECT EASY-PREP System is indicated for the preparation and application of TISSEEL VH Fibrin Sealant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2002

Ms. Arlene Vidor
Vice President, Regulatory Affairs
Baxter Healthcare Corporation
Baxter Bioscience
550 N. Brand Boulevard
Glendale, California 91203-1900

Re: K020666
Trade/Device Name: DUPLOJECT EASY-PREP System
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: May 17, 2002
Received: May 21, 2002

Dear Ms. Vidor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number	K020666
Device Name	DUPLOJECT EASY-PREP Fibrin Sealant Preparation and Application System
Indications for Use	The DUPLOJECT EASY-PREP System is indicated for the preparation and application of TISSEEL VH Fibrin Sealant.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020666